

IN THE CLAIMS:

Please cancel claims 1, 3 through 16, 28, 32, and 42 through 48 without prejudice or disclaimer. Please amend claims 17 through 27, 29 through 31, and 33 through 41, as set forth below, and please add new claims 49 through 53. Applicants note that all claims currently pending in the application are shown below for clarity, except claims 1, 3 through 16, 28, 32, and 42 through 48, which are canceled herein.

Claim 1 and Claims 3 through 16 (Cancelled)

Claim 17 (Currently Amended): A ~~[stable non-aqueous viscous protein]~~ formulation comprising:

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- a) at least one beneficial agent, and
 - b) a non-aqueous single phase biocompatible ~~[viscous]~~ vehicle comprising ~~[two components selected from the group consisting of]~~ solvent, surfactant, and polymer, wherein ~~[the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise, which formulation is capable of being uniformly dispensed over an extended period of time at a low flow rate]~~ the solvent is a lauryl alcohol and the solvent, surfactant, and polymer are selected and formulated such that the vehicle exhibits a viscosity capable of suspending the beneficial agent.

Claim 18 (Currently Amended): A non-aqueous formulation comprising at least one beneficial agent uniformly suspended in a [~~non-aqueous single phase biocompatible viscous~~] vehicle comprising [~~two components selected from the group consisting of~~] solvent, surfactant, and polymer, wherein [~~the two components are not the same and wherein viscosity of the vehicle is between about 1,000 and about 10,000,000 poise, which formulation can be delivered from an implantable drug delivery system such that the exit shear rate of the formulation is between about 1 and 1×10^{-7} reciprocal second~~] the solvent is lauryl alcohol and the solvent, surfactant and polymer are selected and formulated such that the vehicle is a non-aqueous single phase biocompatible vehicle that exhibits a viscosity capable of suspending the beneficial agent.

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cont.
Claim 19 (Currently Amended): The formulation of claim 17, wherein said at least one beneficial agent and said vehicle are selected and formulated such that the formulation is stable at body temperature for extended periods of time.

Claim 20 (Currently Amended): The formulation of claim 17, which comprises at least about 0.1% (w/w) beneficial agent.

Claim 21 (Currently Amended): The formulation of claim 17, which comprises at least about 10% (w/w) beneficial agent.

Claim 22 (Currently Amended): The formulation of claim 17, wherein said beneficial agent is selected from [~~the~~] a group consisting of peptides, proteins, nucleotides, hormones, viruses, [or antibody] and antibodies.

Claim 23 (Currently Amended): The formulation of claim 22, wherein said beneficial agent is a protein.

Claim 24 (Currently Amended): The formulation of claim 17, wherein said at least one beneficial agent and said vehicle are selected and formulated to provide a formulation which is stable at 65° C for at least about 2 months.

Claim 25 (Currently Amended): The formulation of claim 17, wherein said at least one beneficial agent and said vehicle are selected and formulated to provide a formulation which is stable at 37° C for at least about 3 months.

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cont.
Claim 26 (Currently Amended): The formulation of claim 17, wherein said at least one beneficial agent and said vehicle are selected and formulated to provide a formulation which is stable at 37° C for at least about one year.

Claim 27 (Currently Amended): The formulation of claim 17[~~which is~~], wherein said at least one beneficial agent and said vehicle are selected and formulated to provide a formulation adapted for use in an implantable drug delivery device.

Claim 28 (cancelled)

Claim 29 (Currently Amended): The formulation of claim 17, wherein said vehicle comprises an antioxidant.

Claim 30 (Currently Amended): The formulation of claim 17[~~comprising~~], wherein the at least one beneficial agent comprises a beneficial agent which has been dried to a low moisture content prior to incorporation in said formulation.

Claim 31 (Currently Amended): The formulation of claim 17, wherein said at least one beneficial agent and said vehicle are selected and formulated to provide a formulation which is stable after sterilization.

Claim 32 (Cancelled)

Claim 33 (Currently Amended): A method for preparing the stable formulation of claim 17 comprising:

preparing a substantially uniform suspension of the at least one beneficial agent by combining the [single phase viscous] vehicle and the at least one beneficial agent under dry conditions[-and blending them], under vacuum and at elevated temperature [to uniformly suspend the beneficial agent in the vehicle,]; and

allowing the [formulation] suspension to cool to room temperature.

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cont.
Claim 34 (Currently Amended): The method of claim 33 wherein uniformly suspending at least one beneficial agent in the vehicle comprises uniformly suspending at least about 0.1% (w/w) beneficial agent [~~is suspended in said~~] in the vehicle.

Claim 35 (Currently Amended): The method of claim 33 wherein uniformly suspending at least one beneficial agent in the vehicle comprises uniformly suspending at least about 10% (w/w) beneficial agent [~~is suspended in said~~] in the vehicle.

Claim 36 (Currently Amended): A method for treating a subject suffering from a condition which may be alleviated by administration of a beneficial agent comprising administering to said subject a therapeutically effective amount of ~~[the]~~ a formulation [of Claim 17] comprising:

- a) at least one beneficial agent, and
- b) a non-aqueous single phase biocompatible ~~[viscous]~~ vehicle comprising ~~[two components selected from the group consisting of]~~ solvent, surfactant, and polymer, wherein ~~[the two components are not the same and wherein the viscosity of the vehicle is between about 1,000 and about 10,000,000 poise, which formulation is capable of being uniformly dispensed over an extended period of time at a low flow rate]~~ the solvent is a lauryl alcohol and the solvent, surfactant, and polymer are selected and formulated such that the vehicle exhibits a viscosity capable of suspending the beneficial agent.

Claim 37 (Currently Amended): The method of claim 36, wherein said ~~[administration is parenteral administration]~~ method comprises parenterally administering to said subject a therapeutically effective amount of said formulation.

Claim 38 (Currently Amended): The method of claim 36, wherein said ~~[administration is long-term continuous administration]~~ method comprises administering said formulation to said subject continuously over a long-term.

Claim 39 (Currently Amended): The method of claim 36, wherein said ~~[administration is accomplished by use of]~~ method comprises administering said formulation to said subject from an implantable drug delivery system.

Claim 40 (Currently Amended): The method of claim 36, wherein said ~~[daily administration continues]~~ method comprises administering said formulation to said subject daily for a period selected from the group consisting of about 3 months, about 6 months, or about 12 months.

Claim 41 (Currently Amended): The method of claim 40, wherein said ~~[daily administration is accomplished using]~~ method comprises administering said formulation to said subject from an implantable drug delivery system.

Claim 42 through Claim 48 (Cancelled)

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[Please add the following new claims:]

Claim 49 (New): The formulation of claim 17, wherein the vehicle comprises about 30% to about 50% solvent, about 5% to about 20% surfactant, and about 5% to about 60% polymer.

Claim 50 (New): The formulation of claim 17, wherein the polymer is polyvinylpyrrolidone, the surfactant is polysorbate, and the solvent is lauryl lactate.

Claim 51 (New): The formulation of claim 17, wherein the polymer is polyvinylpyrrolidone, the surfactant is gml, and the solvent is lauryl lactate.

Claim 52 (New): The formulation of claim 17, wherein the vehicle includes a surfactant selected from a group consisting of esters of polyhydric alcohols, ethoxylated castor oil, polysorbates, esters or ethers of saturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers.

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Claim 53 (New): The formulation of claim 17, wherein the vehicle includes a polymer selected from a group consisting of polyesters, pyrrolidones, esters or ethers of unsaturated alcohols, and polyoxyethylenepolyoxypropylene block copolymers.
